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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,369	11/13/2001	Donna M. Ferguson	GM50057	1366

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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,369	FERGUSON ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application is a 371 national stage filing of PCT/US00/12133 filed May 4, 2000.

Claims 1-15 are pending .

Election/Restriction

Applicant's election of Group IV, claims 10-14, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). See applicants election filed August 18, 2003, pages 1-2.

Claims 1-15 are pending. Claims 1-9 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse. Claims 10-14 are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Specifically, on pages 31-32, a list of references not provided by Applicants are listed that are not provided in either IDS submitted. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

A signed copy of the IDSs submitted November 13, 2001 and August 21, 2002 are included with the instant action.

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. 37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application. In this case the figures contain multiple sequences that are

not identified in the figures (for example figures 3 and 14) nor the description of the drawings (pages 6-9).

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 10 and 13 are confusing and unclear in how the an antagonist and agonist is related or can have each of the specific characteristics listed in the claim. It is noted that the characteristics are listed in the alternative, however there is no nexus in the claim (nor the specification) between the antagonist/agonist and the activity being set forth. It is unclear if the compound possesses any activity, for example 'binding bacterial 50S ribosomal subunit' (claim 10) if it would be considered an antagonist or an agonist. Further, it is unclear what activity is

being affected among SEQ ID NOs: 1-3. Additionally the recitation of G2061, A2062, G2502, A2407, U2408 are unclear because these compounds are not clearly set forth in the claim nor the specification. Finally, the metes and bounds of the recitation of 'alteration' and 'modulation' are indefinite, confusing and unclear because how much change must be affected is not clearly set forth to meet these limitations of claim.

Claim 11 is incomplete because it is a method without any specific steps set forth. Further, it is unclear what is being treated, how one would suspect infection and which an antagonist or agonist would be used to affect said treatment.

Claim 12 is confusing in its dependence on claim 10 because claim 10 is not a method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Dornhelm *et al.* (Eur J Biochem, 91(2):465-473, November 1978).

Dornhelm *et al.* teach tiamulin , a synthetic pluromutilin, which is a compound that inhibits bacterial chain initiation. The experiments using the compound provide and represent methods for inhibiting.

Claims 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Heman-Ackah (J Pharm Sci. 64(10):1612-20, October 1975).

Heman-Ackah teach the microbial kinetics of drug action against gram-positive and gram-negative bacteria. Specifically, Heman-Ackah study the effect of clindamycin on Staphylococcus aureus and Escherichia coli. Heman-Ackah teach that the activity of clindamycin is due to the ability of the compound to bind to the ribosome as demonstrated by the decreased binding in resistant mutant strains derived from prolonged culture.

Claims 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Weisblum (US Patent 4,376,823).

Weisblum teaches method of increasing the antibiotic resistance of an organism. More specifically, Weisblum teach compounds that bind to the ribosome and are toxic to the bacteria. For example, Weisblum teach erythromycin and teach that it binds to the 50S ribosome subunit (column 5, lines 10-25). Other antibiotics have similar mechanisms are also taught (column 4, lines 14-30).

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by V00348 (NCBI database May 1997).

The sequence disclosed in the sequence listing is the 16S ribosomal RNA of *E. coli*. The sequence is capable of binding other ribosomal protein in the complex.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

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AU1637